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Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/769,621 01/23/01 PARKS

T 10692-005440

EXAMINER

HM12/0927

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ART UNIT

PAPER NUMBER

1614
DATE MAILED:

09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/769,621

Applicant(s)

PARKS ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 34-48 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of application

Acknowledgement is made of preliminary amendment and request for interference filed on July 31, 2001. Original claims 1-33 has been canceled. Claims 34-48 are added and presented for the examination.

Response to the request for interference

Since the claims 34-48 are not deemed to be patentable at this time of prosecution based on USC 103 rejection, the request for interference will not be accepted. It is noted that the exhibition submitted has been reviewed for future consideration for possible interference.

Claim Objections

Claim 37 is objected to because of the following informalities: in line 1, "doxasozin" has incorrectly spelled. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubota et al(11/19/1998) or Bourvier et al (1979) in view of Fogel(US 6,159,944 and 6,117,877), Pasricha et al(US 5,437,291) or Singh et al(US 5,858,371).

Kubota teaches a method of relaxing internal anal sphincter(IAS) and various materials to achieve the said relaxation including α 1 adrenergic antagonist such as phentolamine, tetrodotoxin, atropine; see abstract and page 175 and 178 (Kubota's).

Bourvier also proves α 1 adrenergic antagonist(e.g. phentolamine) being an effective IAS relaxer via *in vivo* and *vitro* test; see summary(page 457-458).

Applicant's claims differ because they are directed to a method of treating painful condition associated with muscle spasm.

However it would have been obvious to one of ordinary skill in the art to modify to

However it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify either Kubota or Bourvier's method so as to include a further teaching as taught in Fogel, Pasricha or Singh because each patentee teaches that the relaxation of IAS is the effective way of treating painful condition associated with muscle spasm. Furthermore each patentee teaches that the pharmaceutical application comprising the cited compounds(e.g. atropine, tetrodotoxin) taught in either Kubota or Bourvier in their patented disclosure. Even if Fogel does not teach α adrenergic antagonist as suggested in applicant's request, Fogel teaches that IAS relaxation is directly involved in treatment of painful condition in anal region. Singh(US371) teaches atropine as an effective material for anorectal disorder including various symptoms(e.g. painful conditions); see claims 2 and 29. Pasricha(US'291) teaches tetrodotoxin and botulinum toxin as an effective material for anorectal disorder; see abstract and column 5, lines 23-68.

One would have been motivated to use for treating painful condition because $\alpha 1$ adrenergic antagonist is proven to be an effective relaxer for sphincter muscle spasm. One would have expected the successful therapeutic outcome, even without the secondary teaching because either Kubota or Bourvier teaches the sphincter muscle relaxation by $\alpha 1$ adrenergic antagonist. With secondary reference support, it is prima facie obvious that the modification of Kubota or Bourvier in view of Fogel, Pasricha or Singh would achieve similar degree of same therapeutic effect because these cited compounds are sharing same biological pathway to achieve the anal sphincter muscle relaxation.

The required species of $\alpha 1$ adrenergic antagonist such as prazosin or doxazosin is substitutable to phentolamine since it is well known in the art (see Heyden:1995, enclosed in PTO-892), and also admitted by applicant in his own disclosure; see instant specification at page 14, line 10.

All the critical elements required in the dependent claims are well taught in the cited references of the record, and thus properly included in this rejection.

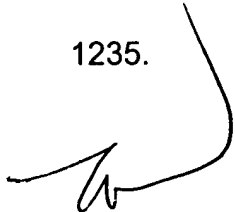
Conclusion

All the pending claims 34-48 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Tuesday-Friday: 8AM-6:30PM) and Fax number is (703) 746-3165.

Art Unit: 1614

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read 'Vickie Kim', with a long, sweeping underline that extends to the right.

Vickie Kim,
Patent examiner
September 20, 2001

A handwritten signature in black ink, appearing to read 'William Jarvis', with a stylized, cursive script.

William Jarvis
Primary examiner
Art unit 1614